

# PRODUCTS LIABILITY LAW REPORTER

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# PRODUCTS LIABILITY LAW REPORTER

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# RECENT CASES

## COMMERCIAL PRODUCTS

### Connecticut recognizes independent tort of intentional spoliation of evidence.

*Rizzuto v. Davidson Ladders, Inc.*, 905 A.2d 1165 (Conn. 2006).

The Supreme Court of Connecticut held the state recognizes an independent cause of action for intentional spoliation of evidence.

The state high court said that the issue is whether the tort is necessary to compensate victims of spoliation and deter future spoliation. The court cited *Beers v. Bayliner Marine Corp.*, 675 A.2d 829 (Conn. 1996), which provides that jurors may draw an inference that the destroyed evidence would have been unfavorable to the destroying party. Under *Beers*, the party complaining of the spoliation cannot build a case on the spoliation inference alone; rather, the party must have some independent, concrete evidence of a product defect.

Here, the court noted, plaintiff alleged defendants' bad faith destruction of a ladder had deprived him of the evidence he needed to establish a prima facie case of products liability. Because the *Beers* inference cannot be invoked by a spoliation victim who has been deprived of the concrete evidence needed to establish his case, the court said the inference provides insufficient compensatory and deterrent effect. Nor are available judicial sanctions such as a default judgment sufficient, the court reasoned, noting that applicability of a default judgment is questionable because of the *Beers* rule that intentional spoliation does not relieve the spoliation victim of the burden of producing concrete evidence to support the underlying claim. The court noted that it would be inconsistent with *Beers* to hold that a victim of spoliation is entitled to judgment as a matter of law despite an inability to satisfy the burden of proof.

Thus, the court concluded, nontort remedies are insufficient to compensate a victim of spoliation who has been completely deprived of his underlying civil action. Nor are they adequate to deter future intentional bad faith spoliation, the court reasoned, noting that the threat of nontort sanctions may pale in comparison to the costs of trial or a substantial damages award.

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Adopting the tort as an independent cause of action, the court held it requires proof of (1) defendant's knowledge of a pending or impending civil action involving plaintiff, (2) defendant's destruction of evidence, (3) defendant's intent to deprive plaintiff of a cause of action, (4) plaintiff's inability to establish a prima facie case without the evidence, and (5) damages.

To establish causation, the court said, plaintiff must prove that defendant's intentional, bad faith destruction of evidence rendered plaintiff unable to establish a prima facie case. Once plaintiff meets this burden, a rebuttable presumption arises that but for the spoliation, plaintiff would have prevailed, and the burden shifts to defendant to rebut the presumption. As for damages, the court held, a successful plaintiff is entitled to recover the full amount of compensatory damages he or she would have received if successful in the underlying action.

*Plaintiff's Counsel*

**Michael L. Oh,**  
**Michael A. Stratton,**  
**Joel T. Faxon,** and  
**Michael R. Denison,** all of New Haven, Conn.

*Comment:* For another case involving an injury from a product in a commercial establishment, see *Montgomery v. Doe Ent. Ctr.*, Cal., Orange Co. Super., No. 02CC10306, Oct. 2004. There, Montgomery was sitting in the patio section of an ice cream parlor when a light fixture's glass globe fell from above and struck her on the head. Montgomery, who was in her 50s at the time of the incident, was diagnosed with posttraumatic cervical nerve root irritation syndrome. Despite surgery, she continues to suffer pain and neurological problems. Her medical expenses totaled \$66,000. She was unemployed at the time of the incident.

Montgomery and her husband sued the manufacturers of the light fixture and globe, alleging they were defective, and the company that installed them, alleging they had been improperly installed. Plaintiffs also sued the local entertainment center where the ice cream parlor was located, alleging it had final control over the fixture and globe.

Defendants argued that Montgomery's medical problems were preexisting and that the weight of the globe and the distance it fell were not great enough to cause the alleged injuries.

The parties settled for \$150,000.

Plaintiffs' experts were John Brault, biomechanics, Lake Forest, Cal.; Gerald Zamiski, accident reconstruction, Long Beach, Cal.; Catherine Graves, economics, Fullerton, Cal.; and Martin Levine, neurology, Encino, Cal.

Plaintiffs in the *Montgomery* case were represented by **Christopher R. Aitken**, Santa Ana, Cal.

## CONSUMER PRODUCTS

### Comparative fault principles apply to participants in production chain of allegedly defective product.

*State Farm Ins. Cos. v. Premier Mfd. Sys., Inc.*, 142 P.3d 1232 (Ariz. App. 1st Div. 2006).

An Arizona appellate court held that the state's statutory comparative fault scheme applies to the participants in the chain of production of an allegedly defective product.

After paying benefits to an insured who suffered property damage from a defective water filtration system, the insurer sued the company that packaged and sold the system and the manufacturer of one of the system's components. The court entered a default judgment against the manufacturer, which was defunct, and the seller asserted that the jury should have to determine the parties' relative degrees of fault. Plaintiff moved for summary judgment, arguing that all entities in the chain of distribution are jointly and severally liable. The trial court denied the motion, holding that comparative fault principles set forth in Ariz. Rev. Stat. § 12-2506 apply to strict products liability cases and that the entities in the chain of distribution are severally liable. The parties then stipulated that the seller was 25 percent at fault, and the court entered judgment reflecting the seller's proportionate share.

Affirming, the appellate court noted that in 1987, the state legislature amended the statutory scheme, eliminating joint and several liability except in certain situations and replacing it with a system of several liability based on comparative fault. The court rejected plaintiff's argument that when a plaintiff's injuries are caused by a defective product and the only parties at "fault" are those in the chain of distribution, those parties should be jointly and severally liable because to hold otherwise would undermine the policy reasons behind strict liability. The statute clearly requires the fault of all members of the distribution chain to be compared and allocated, the court said.

## DRUGS

### Plaintiff raised fact question as to whether drug manufacturer failed to adequately warn of risk from drug's long-term use.

*McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006).

The Fifth Circuit Court of Appeals held that a plaintiff in a lawsuit against the manufacturer of the drug

Reglan raised fact questions regarding whether defendant failed to adequately warn of the risk of developing tardive dyskinesia from long-term use of the drug, where the label's statement that the risk was "higher" with extended use may not have accurately conveyed the nature of the risk.

After taking the drug for 14 months to treat symptoms of gastroesophageal reflux disease, McNeil developed tardive dyskinesia, a severe nervous system disorder. In her lawsuit against the manufacturer, plaintiff alleged that the drug's label failed to adequately warn about the increased risk associated with exposure to the drug for more than 12 weeks. The trial court granted defendant's motion for summary judgment, ruling that the label was adequate as a matter of law because it stated that the drug was intended for short-term use of 12 weeks or less, warned about the potential risk of tardive dyskinesia, and cautioned that the risk increases with the duration of treatment and total cumulative dose.

Reversing, the Fifth Circuit noted plaintiff is arguing that the warning is inadequate not because her condition was not mentioned, but because it is misleading as to the risk level for developing the condition. Finding no Texas case law permitting a finding of adequacy as a matter of law in this situation, the court said it would apply the default rule that questions of adequacy are for the jury to decide.

The court rejected defendant's argument that it does not have a duty to warn about the risks of use longer than 12 weeks because the label clearly warns that the drug is not intended for longer duration. Citing plain-

tiff's expert testimony that defendant's own market data showed 84 percent of people were using Reglan long-term, the court reasoned that defendant knew, or should have known, that the drug was routinely prescribed for long-term use.

The court next noted that because defendant advertised the risk of developing tardive dyskinesia as "comparatively rare," or 0.2 percent for short-term use, simply stating that the risk increases with use does not put a physician on notice that studies have found that the risk can be 100 times higher. Thus, the court concluded, a jury could find that the risk was not just higher, but that it was "significantly" higher, and that the label was therefore misleading and inadequate.

*Plaintiff's Counsel*

**John Alan Jones,**  
Coleman M. Cowan, and  
**George Christopher Olson,** all of Raleigh, N.C.

### Common law claims alleging injuries from diabetes drug Rezulin are not preempted.

*Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

The Second Circuit Court of Appeals held that federal law does not preempt a statutory exception to Michigan state law, which immunizes drug manufacturers from liability where the FDA has approved a drug.

Here, in a case involving the diabetes drug Rezulin, plaintiffs invoked Mich. Comp. Laws § 600.2946(6), which preserves liability where the manufacturer engaged in fraud to procure the FDA's approval.

Defendant cited *Buckman Co. v. Plaintiffs' Leg. Comm.*, 531 U.S. 341 (2001), 20 PLLR 47 (Apr. 2001), in which the U.S. Supreme Court held that state "fraud-on-the-FDA" claims are preempted by federal law. Defendant also cited *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), 24 PLLR 6 (Feb. 2005), which held based on *Buckman* that the fraud exception in Michigan's statute was impliedly preempted by federal law and therefore had to be severed from the rest of the statute. The trial court agreed and concluded the exception should be severed.

Reversing, the Second Circuit rejected defendants' argument that, notwithstanding *Garcia's* statement that the Michigan statute does not create a specific cause of action for fraud on the FDA, there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and the nature of the claim preserved by the exception in § 600.2946(6).

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First, the court noted, the Court in *Buckman* found that the presumption against preemption did not apply because policing fraud against federal agencies is not an area traditionally occupied by the states. Here, by contrast, the cause of action that survives cannot reasonably be characterized as a state's attempt to police fraud against the FDA. Rather, the purpose of the Michigan statute is simply to regulate and restrict when plaintiffs may continue to recover under preexisting state products liability law.

Second, unlike in *Buckman*, plaintiffs here are asserting not fraud-on-the-FDA claims, but a wide range of common law claims premised on traditional duties manufacturers owe Michigan consumers. Finally, unlike the claims in *Buckman*, proof of fraud against the FDA is not even an element of plaintiffs' claims here, and the existence of properly obtained FDA approval becomes germane only if a defendant chooses to assert it as an affirmative defense, the court held.

Reasoning that to find preemption of traditional common law claims where fraud is not even a required element "would result in preemption of a scope that would go far beyond anything that has been applied in the past," the court concluded plaintiffs' claims should proceed.

*Plaintiffs' Counsel*

David B. Rodes, Pittsburgh, Pa.

**Vincent J. Carter**, Los Angeles, Cal.

**David R. Parker**, Detroit, Mich.

Jerome D. Goldberg, Southfield, Mich.

*Comment:* The court also held that it was not bound by a sister circuit court's ruling even though the sister court was interpreting the laws of a state within its own circuit. A summary of the court's ruling on that issue will appear in the Practice & Procedure section of an upcoming issue of *Law Reporter*.

**No federal jurisdiction where drug manufacturer failed to prove "federal officer" provision applied or nondiverse defendant fraudulently joined.**

*Stanley v. Wyeth Inc.*, \_\_\_ F. Supp. 2d \_\_\_, 2006 WL 2588147 (E.D. La. Sept. 8, 2006).

A U.S. district court remanded a lawsuit against a drug manufacturer to state court, holding that federal jurisdiction was lacking because the case did not fall within the removal statute's "federal officer" provision and the manufacturer failed to prove fraudulent joinder of the nondiverse pharmacist defendant.

Here, Arculeer developed liver complications and died after taking the prescription generic drug amio-

darone. In her survivors' Louisiana state court suit against the manufacturer, plaintiffs joined the Louisiana pharmacist who filled the prescription, alleging she failed to include an FDA-required patient insert containing warnings. After defendants removed the case, the federal court *sua sponte* raised the issue of whether it had jurisdiction over the case.

Concluding it lacked jurisdiction, the court rejected the manufacturer's argument that the case falls within the "federal officer" removal provision of 28 U.S.C. § 1442(a)(1) because it was required by law to give the exact warning authorized by the FDA, and, therefore, the claims against it are actually an attack on the FDA's decisions about the label's content or the drug's safety. The cases on which it relies, in which private manufacturers were found to have acted essentially as government employees, all involved situations in which the government had contracted with a private company and exercised control over its actions. Here, there was no evidence the FDA had asked it to make or sell the drug.

The court also rejected the argument that federal jurisdiction was proper based on diversity of citizenship because the in-state pharmacist was fraudulently joined to defeat diversity. To establish federal jurisdiction, a defendant bears the heavy burden of showing that there is no possibility plaintiff would be able to establish a cause of action against the nondiverse defendant in state court. Any contested issues must be resolved in plaintiff's favor.

Noting that, generally, pharmacists are protected by the learned intermediary doctrine and have no duty under state law to warn of a drug's dangers, the court cited *Alman v. GlaxoSmithKline Corp.*, 2002 WL 465202 (E.D. La. 2002). There, the court held that Louisiana follows the "uniform national rule" that a pharmacist has no duty to warn where the prescription is valid on its face and "neither the physician nor the manufacturer has required that the pharmacist give the customer any warning." In *Alman*, the court held that because the patient insert advised the patient to ask the pharmacist about possible side effects, and the pharmacist knew the warning was inadequate, plaintiff raised a fact question as to whether the manufacturer had required the pharmacist to give further warnings.

Here, the court noted, it did not have the insert and therefore could not determine whether the manufacturer requires the pharmacist to include it. If the insert instructs the patient to ask the pharmacist for further details, or if the manufacturer requires the pharmacist to include the insert, the court reasoned, plaintiffs may be able to state a claim.

*Plaintiffs' Counsel*

**David Alan Abramson**, New Orleans, La.

**Lawrence S. Kullman**, New Orleans, La.

## INDUSTRIAL PRODUCTS & EQUIPMENT

### **Asbestos plaintiff's failure to recall defendant's name or product did not shift burden to plaintiff to show fact question on causation.**

*Weber v. John Crane, Inc.*, 50 Cal. Rptr. 3d 71 (Cal. App. 1st Dist. 2006).

A California appellate court held in a lawsuit against an asbestos product manufacturer that a plaintiff's deposition testimony that he could not recall the manufacturer's name or whether he had ever worked with its products did not shift the burden on defendant's summary judgment motion to plaintiff to show that a material fact question existed on causation.

Here, Weber and his wife sued John Crane, Incorporated, among other asbestos product manufacturers, alleging Weber's exposure to the products had caused him to develop mesothelioma. At deposition, Weber testified that he had not heard of the name "John Crane" and did not recall working with any products by the company. Defendant moved for summary judgment, arguing that there was no triable issue of fact that it was a cause of Weber's disease. The trial court granted the motion, concluding the relevant case law established that Weber's inability to recall a connection between himself and defendant's product shifted the burden of production to plaintiffs.

Reversing, the appellate court said the trial court misinterpreted the case law, which does not establish that a defendant shifts the burden of production to a plaintiff merely by showing that the plaintiff has no personal recall of defendant's product. Rather, a defendant must show that the plaintiff will be unable to prove the case by *any* means. Here, the court said, the fact that Weber was unable to recall whether he worked around a John Crane product more than 40 years earlier suggests only that plaintiffs will not be able to prove their case through his deposition testimony. It cannot be inferred that there is no witness or other evidence linking defendant to Weber's job site or that he would have been unable to identify one of defendant's products if it had been shown to him.

The court distinguished cases in which defendants were found to have shifted the burden of production, noting that the plaintiffs in those cases had either failed to provide meaningful responses to comprehensive interrogatories or had been able to specifically identify certain products and brand names, creating an inference that the products not recalled had not been used.

*Plaintiffs' Counsel*

**Philip A. Harley**, Berkeley, Cal.

Deborah R. Rosenthal, Berkeley, Cal.

### **Scissors lift: Inadvertent activation: Inadequate instructions: Improper assembly: Fractures: Settlement: Postverdict structured settlement.**

*Lombardi v. Am. Lifts, Ill.*, Cook Co. Cir., No. 02 L 7241, July 18, 2006.

Lombardi, 40, was working at a scissors lift at the end of an assembly line that produced laminated boards for counter tops and cabinets. As he was guiding a board onto the lift table, he inadvertently stepped on the machine's foot pedal located underneath the table. The loaded table, which weighed more than 1,500 pounds, lowered onto his right leg.

Lombardi suffered a comminuted fracture of the right tibial plateau and a bimalleolar fracture of the right ankle. He underwent six surgeries and ultimately required fusion of the right knee joint, which has left him unable to bend his leg at the knee. He has difficulty walking and suffers back pain as a result of his impaired gait. He also has difficulty sitting for long periods. His medical expenses totaled about \$505,300. An assembly line worker earning \$18,300 annually, he has been unable to return to work, and his chances for securing future employment are limited.

Lombardi sued the manufacturer of the lift, alleging it was unreasonably dangerous in that it lacked adequate instructions warning against placing the foot pedal underneath the lift table. Plaintiff also sued the company that manufactured the other components of the assembly line and assembled the line, including the scissors lift, alleging strict liability for providing a dangerous configuration with the pedal located under the lift table.

Defendants brought a third-party claim against plaintiff's employer, arguing that it failed to train him how to use the equipment properly and that it should have affixed the pedal to an area away from the underside of the lift table.

Defendants also argued that because plaintiff had injected the contents of Oxycontin tablets, rather than taking them orally as his physician had prescribed, he developed a bloodstream infection resulting in osteomyelitis in the knee. Defendants argued that \$90,000 of plaintiff's medical expenses were related to treating the infection and were not their responsibility.

Finally, defendants asserted that plaintiff was negligent in operating the equipment with the foot pedal under the lift table. Plaintiff countered that under Illinois law, an employee is not subject to comparative negligence for operating machinery in the manner directed by his or her employer.

Plaintiff's employer settled before trial by waiving

## RECENT CASES

approximately \$173,700 of a workers' compensation lien totaling about \$323,700.

The jury awarded about \$1.89 million before apportionment of liability. The addition of prejudgment interest brought the award to about \$1.9 million. The jury found the assembler 35 percent liable, plaintiff's employer 35 percent at fault, the lift manufacturer 25 percent liable, and plaintiff 5 percent responsible. The parties agreed to disregard the comparative negligence finding and placed \$450,000 of the verdict amount into an annuity yielding about \$2,000 monthly, increasing 3 percent annually, for life.

Plaintiff's expert was James Des Jardins, mechanical engineering, Chicago, Ill.

The manufacturer's expert was Russ Rasnic, mechanical engineering, Hot Springs, Ark.

*Plaintiff's Counsel*

**Edmund J. Scanlan**, Chicago, Ill.

### **Asbestos-coated piping: Negligent exposure of contract worker: Wrongful death: Settlements: Verdict.**

*Terrance v. Exxon Mobil Corp.*, La., 19th Jud. Dist., Div. D, No. 504,016, June 24, 2006.

While working as a contract laborer at Exxon for various periods between 1965 and 1970, Terrance tore off asbestos-coated pipes without wearing any respiratory protection. In 2002, at age 62, he was diagnosed with mesothelioma. His illness forced him to quit work, and he died six months later, at age 63. His medical expenses were about \$35,300. Terrance is survived by his wife and four adult children. His lost wages totaled about \$20,000.

Terrance's wife, on behalf of his estate, sued Exxon, alleging defendant was negligent in exposing Terrance to asbestos with knowledge of the dangers, in violation of the company's own internal rules.

Plaintiff also sued the manufacturers of various asbestos products to which Terrance had been exposed, as well as various contractors for whom he worked. These defendants settled for confidential amounts before trial, and the case proceeded solely against Exxon.

Defendant denied causation and argued that other third parties were responsible or that Terrance was contributorily negligent in not wearing protective gear. In response, plaintiff argued that defendant was a sophisticated user and knew about the dangers of asbestos by 1964, and probably as early as 1937.

The jury awarded about \$5.1 million, finding Exxon

100 percent at fault. The court subsequently denied defendant's motions for a new trial, remittitur, or fault against third parties, and defendant has filed a notice of appeal.

Plaintiff's experts were Frank M. Parker III, industrial hygiene, Magnolia, Tex.; Richard Hatfield, materials analysis, Atlanta, Ga.; Barry I. Castleman, Exxon's asbestos history, Baltimore, Md.; Victor L. Roggli, pathology, Durham, N.C.; and Bolling C. Haygood, pulmonology, Baton Rouge, La.

Defendant's experts included Michael J. Warhol, pathology, Philadelphia, Pa.; and Francis Weir, industrial hygiene, Houston, Tex.

*Plaintiff's Counsel*

**Lewis O. Unglesby**,

**Robert M. Marionneaux Jr.**,

**Samuel C. Ward Jr.**, and

John F. McKay, all of Baton Rouge, La.

*Comment:* During trial, one of the jurors was excused for health problems, leaving only 11, as there was no alternate juror. Defendant sought a mistrial. The trial court denied the motion, but an appellate court reversed and granted the motion. The state high court reinstated the trial court's ruling and held that the trial could proceed. *Terrance v. Dow Chem. Co.*, 930 So. 2d 961 (La. 2006).

## MEDICAL PRODUCTS & EQUIPMENT

### **Plaintiff raised fact questions regarding whether nerve-lesioning device was unreasonably dangerous and had inadequate warning.**

*Tingey v. Radionics*, \_\_\_ F.3d \_\_\_, 2006 WL 2258872 (10th Cir. Aug. 8, 2006).

Tingey underwent nerve ablation surgery, a procedure in which a doctor uses a radiofrequency lesion generator to isolate and destroy painful nerve tissue. The process requires adjustments in frequency, which is controlled by a rate-select button, and in voltage, which is controlled by both a knob that increases the settings incrementally and a toggle that immediately increases the voltage tenfold. The frequency button has a fail-safe mechanism that shuts off the device if the operator attempts to switch frequencies when the voltage control knob is not set to zero. The voltage toggle does not have a safety backup, however. To avoid delivering a sudden, tenfold increase in voltage to the patient, the operator must either reset the voltage-control knob to zero before switching to the toggle or

activate the frequency button before the voltage knob, which will cause the fail-safe mechanism to shut off the machine.

During Tingey's procedure, the assisting nurse activated the toggle without first turning the voltage knob to zero or activating the frequency button. As a result, Tingey received a shock that allegedly caused neurological damage. She sued the manufacturer of the device, alleging design defect and failure to warn, among other claims. The trial court granted defendant's motion for summary judgment.

Reversing in part, the Tenth Circuit noted that to establish strict liability for design defect under Utah law, a plaintiff must prove that the product in question is unreasonably dangerous due to a defect existing at the time of sale. The test has both an objective component, which asks whether the product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer, and a subjective component, which requires consideration of the particular user's knowledge, training, or experience.

Here, plaintiff alleged that the device is designed so that it automatically shuts off if any change in output other than that created by operation of the toggle is made without first adjusting the voltage knob to zero. Although the assisting nurse testified that she was trained to turn down the voltage before changing the output, there is no evidence she was aware that the toggle was not protected by the automatic shutoff safety mechanism or that failing to zero out the voltage could cause the patient to suffer a harmful shock. Thus, the court concluded, plaintiff had raised a fact question regarding whether the device was more dangerous than an ordinary user would anticipate. Plaintiff also met her burden under the subjective test, the court said, because there was no evidence that the nurse's training would have alerted her to the specific danger here. The court added that plaintiff was required to satisfy a risk-utility test by proving the practicability of a safer design, which she did by offering evidence that the device could still perform its essential functions without a toggle.

Turning to the failure to warn claim, the court rejected defendant's argument that it had no duty to warn because the danger was not reasonably foreseeable and resulted from the nurse's multiple errors. Noting that a manufacturer has a duty to warn of potential dangers from reasonably foreseeable misuse of a product, the court said the concept of foreseeable misuse has been extended to mishaps involving a combination of factors.

*Plaintiff's Counsel*

**Robert B. Sykes**, Salt Lake City, Utah

**Kevin M. Sheff**, Salt Lake City, Utah

## RECREATIONAL PRODUCTS

### Sophisticated user doctrine applies in breach of warranty claim alleging failure to warn of bungee cord's dangers.

*Carrel v. Natl. Cord & Braid Corp.*, 852 N.E.2d 100 (Mass. 2006).

The Supreme Judicial Court of Massachusetts held that the sophisticated user doctrine is a defense to a claim alleging breach of implied warranty for failure to warn and that the doctrine applies in a case against a bungee cord manufacturer for injuries to a camper struck by a cord because the camp organizer, not the camper, was the end user of the product.

Here, Carrel was injured while participating in a "zip-line" course at a Boy Scout camp when a knot in the bungee cord he was holding came loose and struck him in the eye. He filed suit against the cord manufacturer, alleging breach of implied warranty for failure to warn of the cord's dangers. Defendant raised the sophisticated user doctrine, and the court instructed the jury that defendant's duty to warn might be reduced or eliminated if the end user's experience, expertise, and knowledge exceeded the manufacturer's. The jury found for defendant.

Affirming, the state high court first held that the sophisticated user doctrine applies both in negligent failure to warn claims as well as in breach of warranty claims based on failure to warn, citing case law in which it has held that the two theories are to be judged under the same standard.

The court next rejected plaintiff's argument that the doctrine should not apply here because he was the relevant end user, and there was no evidence he was a sophisticated user of the product. Plaintiff tried the case on the theory that the Boy Scouts, and, to a lesser extent, the company that had supplied the cord, were the end users, the court said. The trial court's instruction made clear that it was the scouting organization's level of sophistication that was at issue, and plaintiff failed to object to the instruction.

The court also rejected plaintiff's argument that there was insufficient evidence to warrant giving a sophisticated user instruction, noting that defendant had offered evidence that the Boy Scouts ran similar programs with zip-line activities throughout the country, had national safety standards, and employed specialists to inspect and ensure compliance with those standards.

Finally, the court rejected plaintiff's argument that the trial court's instruction may have caused the jury to confuse the Boy Scouts' skill and experience in tying

knots and using bungee cords with their knowledge of the cords' latent properties and dangers. Noting that in the context of the entire instruction, the reference to the user's expertise clearly applied to the dangers posed by the product's latent properties, the court said it is not necessary that the user know the exact characteristics of the product that make it dangerous. It is sufficient that the user knew or reasonably should have known of the particular danger to be guarded against.

*Comment:* For other bungee cord cases, see *Dudley v. Bungee Intl. Mfg. Corp.*, 76 F.3d 57 (4th Cir. 1996), 15 PLLR 39 (Mar. 1996), and *Hahn v. L.C. Indus.*, 19 PLLR 129 (Aug. 2000). Documents in both cases are available through the Court Documents section at p. 18, courtesy of plaintiffs' counsel.

### **Snow ski: Ski delaminates during use: Skier thrown: Sale of defective ski: Tibial fractures: Knee injury: Settlement.**

*Beety v. Sportmart, Inc.*, Wis., Milwaukee Co. Super., No. 05-CV-001-212, May 9, 2006.

Beety, 43, purchased a pair of skis imprinted with the Dynastar name and transferred the bindings from his old pair of skis onto the new ones, a procedure he had performed numerous times in the past. Several days later, while skiing on a well-groomed slope during good weather, he shifted his weight to his right ski in preparation for a turn. He heard a loud snap and was thrown forward over the top of his skis.

Beety suffered severe fractures to his right tibia, resulting in crushing of the tibial plateau. He was placed in an external fixation device for about three months, and then a long leg cast for about another month-and-a-half. In addition to the bone fractures, he suffered tissue damage in and around his muscles, ligaments, tendons, veins, and arteries and required four surgeries, including a total right knee replacement. He now suffers from chronic pain in the knee and daily swelling after use. His past medical expenses totaled \$139,000, and his future anticipated medical expenses, based on the likely need for a future knee replacement, are estimated at \$50,000. A surveyor, his past lost wages totaled \$92,000.

Examination of the right ski revealed that it had snapped in flexion about a foot from the tip, causing the rest of the ski to dig into the snow and stop. As Beety was thrown forward over the top of his skis, the right ski delaminated and separated beneath his right boot. As a result, he could not provide sufficient kick to release the bindings, which did not release until after his right knee was completely hyperextended.

Beety sued the sole U.S. distributor of the ski and the retailer that sold it, alleging strict liability and negligence for distributing and selling a defective ski. Plaintiff released the distributor after the company offered evidence it had not imported and sold this particular model of Dynastar ski and was not in the chain of distribution.

Plaintiff's expert could find no identifiable reason why the ski tip broke and no signs of misuse, dents, or divots indicating the ski had struck an object. He was prepared to testify that the fracture of the new ski under relatively benign use must have resulted from poor material selection, poor adhesives, poor manufacturing techniques, or a combination of such manufacturing defects.

During discovery, plaintiff learned that the retailer could find no records or documents showing it had acquired the ski. The lack of documents of origin, together with evidence that the skis (1) had not passed through the sole U.S. distributor; (2) had no serial number, which typically would have been stamped into the sidewall by the manufacturer; (3) were sold as a sale item for under \$20 when they normally retailed for more than \$400; and (4) were supposedly a well-regarded brand but had failed within the first several hours of use all led to the implication that the skis may have been counterfeits manufactured by an entity other than Dynastar.

Defendant argued that the ski must have struck an object.

The parties settled during mediation for \$420,000.

Plaintiff's expert was Seth Bayer, skis, LaFayette, Colo.

Defendant's expert in this case was Helge Lien, skis, Lancaster, Pa.

*Plaintiff's Counsel*

**Victor C. Harding**, Milwaukee, Wis.

**William Fix**, Jackson Hole, Wyo.

## TRANSPORTATION

### **Pickup truck: Rollover: Seat belt fails to unlatch: Drowning: Settlement.**

*Kelley v. Ford Motor Co.*, Fla., Palm Beach Co. 15th Jud. Cir., No. 50 2005 CA 008416 XXXXMB AD, Mar. 2006.

Kelley was driving a 2002 Ford F-250 pickup truck when the truck hit a puddle of water, began hydroplaning, and rolled over into a drainage ditch. She struggled to free herself as water began filling the passenger compartment, but she was unable to release her seat belt and drowned. Kelley was in her

mid-30s at the time of the incident and working as a dental hygienist earning just under \$40,000 annually. She is survived by her husband and two minor sons.

Kelley's husband, individually and on behalf of her estate and minor children, sued the manufacturers of the truck and seat belt, alleging the seat belt latch was defectively designed in that it would not release when in an inverted position.

The parties settled for a confidential amount.

Plaintiffs' experts were Ronald Kirk, accident reconstruction, Raleigh, N.C.; Rudolf Limpert, tires and brakes, Park City, Utah; Craig Good, seat belts, Calgary, Alb., Can.; and Richard Clarke, restraints, Hoschton, Ga.

*Plaintiffs' Counsel*

**Theodore J. Leopold**, Palm Beach Gardens, Fla.

### **SUV: Vehicle accelerates out of control: Defective cruise control system: Wrongful death: Partial paralysis: Verdict.**

*Watson v. Ford Motor Co.*, S.C., Greenville Co. Cir., No. 2002-CP-23-8147, Aug. 6, 2006.

Watson, 17, was driving a 1995 Ford Explorer XLT SUV with the cruise control on when the vehicle suddenly accelerated out of control. The SUV allegedly reached speeds of 80 m.p.h. before crashing and rolling over. Watson and her aunt, Carter, 55, who was sitting in the left rear passenger seat, were both ejected. Carter suffered fatal injuries. She had previously worked at a nursing center but was not employed at the time of the incident because of kidney problems. She is survived by her husband and adult son.

Watson suffered a spinal fracture at C4-5, resulting in incomplete quadriplegia. She requires 24-hour care, but she has some use of her arms and is able to drive using a specially modified automobile. She also attends a community college with assistance from adaptive technology such as a voice-activated wheelchair and computer system, and she hopes to pursue her career plans of teaching early education. Her past medical expenses totaled about \$1 million, and her future medical expenses and life-care costs are estimated at about \$8 million.

Watson and Carter's husband, on behalf of her estate, sued the manufacturer of the SUV. Plaintiffs alleged that the cruise control system was defective in that it permitted the errant electrical signals that are present in all automobiles to affect the electrical functions of the cruise control. This electrical magnetic interference (EMI) causes the cruise control to malfunction and "freeze" in wide open throttle, plaintiffs

claimed, leaving it frozen in the open position until the system is disconnected from the electrical source. Plaintiffs claimed that defendant could have prevented the problem by simply changing the wiring of the system's speed control sensor so that it could resist the errant electrical signals.

Plaintiffs offered evidence that defendant used the alternative wiring solution on its speed sensors for brake functions and that defendant had conducted an investigation into sudden acceleration complaints in England. Plaintiffs also obtained e-mails confirming that defendant concluded the problem of sudden acceleration is caused by EMI and is easy to fix.

Other evidence showed that the vehicle had had two prior problems with sudden acceleration and that Watson's father had taken it in for repairs but was told that the floor mat interfered with the accelerator pedal.

The jury awarded \$15 million to Watson and \$3 million to Carter's estate. The court subsequently denied all of defendant's posttrial motions, and defendant is expected to appeal.

Plaintiffs' experts were Bill Williams, cruise control and brake systems, Georgetown, S.C.; and Anthony Anderson, electrical engineering, Gosforth, Newcastle upon Tyne, Eng., U.K.

Defendant's experts were Donald Struble, restraints, San Luis Obispo, Cal.; and Karl Passegger, cruise control systems, Detroit, Mich.

*Plaintiffs' Counsel*

**J. Edward Bell III**, Georgetown, S.C.

**James W. Fayssoux Jr.**, Greenville, S.C.

**Kevin R. Dean**, Mount Pleasant, S.C.

### **SUV: Child trapped after activating power window: Defective design using unrecressed toggle switch: Wrongful death: Settlement.**

*Michael v. Ford Motor Co.*, Ariz., Maricopa Co. Super., No. CV2005-051546, Sept. 7, 2006.

Michael's mother placed her in her child safety seat in the family's 2001 Ford Excursion SUV and drove to the family's barn to supervise delivery of a load of hay. She parked the vehicle, leaving it running to keep it from getting too hot inside, and left to supervise the delivery. Michael, who was not fastened into the seat, inadvertently activated the passenger side rear power window. Her head became trapped in the window, and she was strangled. Michael was 21 months old and is survived by her parents and minor brother.

Michael's father, individually and on behalf of her estate, and her mother sued the manufacturer of the

vehicle, alleging that the unrecessed, toggle-type power window switch was defective and unreasonably dangerous in that minimal pressure, such as contact by a child's knee or foot, released deadly energy. Plaintiffs were prepared to present expert testimony that the power windows in most current vehicles have the motor power to raise a smaller child's body and that when a two-pound downward force is exerted on the toggle switch in the vehicle here, the activated window exerts an upward force of between 50 and 80 pounds. Because only eight to 12 pounds is required to lift the glass, plaintiffs argued, the excess available force of between 40 and 70 pounds is more than enough to lift and strangle a child.

Plaintiffs were also prepared to show that because the window rises in just two to four seconds, it can trap a child's head or neck before the child has time to move out of the way.

Plaintiffs argued that defendant and the automotive industry in general have known for decades of the dangers of power windows and that since their introduction into the U.S. market without any safety controls in the late 1950s and early 1960s, more than 60 children have died in power-window-related incidents.

The parties settled during mediation for a confidential amount.

Plaintiffs' expert was Thomas P. Flanagan, power windows, Carlsbad, Cal.

*Plaintiffs' Counsel*

**Robert M.N. Palmer**, Springfield, Mo.

**Scott A. Smith**, Springfield, Mo.

**David W. Little**, Oklahoma City, Okla.

### **Pickup truck: Fuel tank ruptures on impact: Post-impact fire: Dangerous location of tank outside frame rails: Burns: Settlement.**

*Thornton v. Gen. Motors Corp.*, Mo., Cole Co. Cir., No. 04-CV-324706, Mar. 27, 2006.

Thornton, 16, was driving on a state highway when a 1979 GMC Sierra 3/4 ton pickup truck traveling on an intersecting road pulled out in front of her at an uncontrolled intersection, and the vehicles collided. On impact, the pickup truck's fuel tank ruptured, and gasoline splashed onto and under Thornton's car. The gas ignited, and the car was engulfed in flames.

Thornton suffered burns, mostly third-degree, over 40 percent of her body, including her legs, feet, arms, hands, and lower torso. She required extensive skin grafting and now has scars to both the burned areas and the areas used as skin-graft donor sites. She also suffers

from sensitivity to heat and cold. Her past medical expenses totaled about \$600,000, and her future medical expenses are estimated at about \$1.52 million. A high school student who was earning \$5.15 hourly working part-time at a pizzeria, her future lost income is estimated at between \$1.68 million and \$1.76 million.

Thornton's mother, on her behalf, sued the manufacturer of the truck, alleging it was defectively designed in that the fuel tank was mounted on the side of the truck outside the frame rail, leaving it vulnerable to rupture or puncture in the event of a foreseeable collision. Plaintiff was prepared to offer evidence that the impact was a low-speed collision and that, but for the post-impact fire, she would have walked away without injury. During discovery, defendant produced records of more than 800 similar incidents.

Defendant denied that the truck was defective and argued that it had been altered after its sale. Specifically, defendant claimed that the tank had been patched at some point before the collision and that the patch had been knocked loose during the impact, exposing a hole that was the source of the leak.

The parties settled at mediation for a confidential amount.

Plaintiff's experts included William R. Bush, fire cause and origin, Birmingham, Ala.; Bruno Schmidt, accident reconstruction, Springfield, Mo.; Jerry G. Wallingford, fire cause and truck design, San Antonio, Tex.; and Terry Winkler, life-care planning, and Dale A. Halfaker, neuropsychology, both of Springfield, Mo.

Defendant's experts were Richard A. Dyer, fire source and origin, Lee's Summit, Mo.; Dennis A. Guenther, crashworthiness and fuel system design, Columbus,

### **DON'T MISS THE NEWS**

The new AAJ L@w News Digest is a weekly summary of news and cases of interest to plaintiff lawyers delivered to members via e-mail. The digest includes summaries of articles from major national, state, and professional publications. It also updates readers on recent litigation and AAJ's lobbying and legal affairs efforts. To get the AAJ L@w News Digest delivered to your computer, send your name, member ID number, telephone and fax numbers, and e-mail address to [member.updates@justice.org](mailto:member.updates@justice.org), or fax the information to (202) 298-6849.

Ohio; Michael P. Holcomb, accident reconstruction, Rochester Hills, Mich.; Alan W. Thebert, vehicle design and failure analysis, Shelby Township, Mich.; and William E. Wecker, statistics, Novato, Cal.

*Plaintiff's Counsel*

**Randy W. James,**

**Mark E. Parrish,** and

**Lauren Perkins Allen,** all of Lee's Summit, Mo.  
W. Swain Perkins, Thayer, Mo.

### **SUV: Rollover: Roof crushes in on driver: Insufficient roof strength: Inadequate occupant restraint system: Quadriplegia: Settlement.**

*Lu v. Nissan Motor Co.*, Wash., King Co. Super., No. 04-2-16526-1 SEA, Mar. 1, 2006.

Lu, 40, was driving a 1995 Nissan Pathfinder SUV when the vehicle left the roadway and rolled over several times. During the rollover, the roof crushed in on Lu, and he suffered a spinal fracture at C5-6, rendering him quadriplegic. He also suffered a mild traumatic brain injury, a crush injury to his left hand, bilateral pulmonary contusions, a rib fracture, and neurogenic bowel and bladder. His medical expenses totaled \$397,000, and his future anticipated medical expenses and life-care costs are estimated at \$5 million. A computer service technician earning \$50,000 annually, he has not returned to work.

Lu sued the manufacturer of the SUV, alleging it was uncrashworthy in that the roof was not sufficiently strong to withstand the forces of the rollover without intrusion into the occupant survival space. Plaintiff argued that roof structures must be able to withstand at least three times the weight of the vehicle in a Federal Motor Vehicle Safety Standard 216 test without deformation into the occupant survival space but that the vehicle here failed to meet this and other safety criteria. Plaintiff claimed safer alternative designs would have included (1) closed header sections rather than open sections; (2) thicker sheet metal; (3) B-pillar to B-pillar reinforcements, such as box-section roof bows; and (4) foam-filled pillars.

Plaintiff also alleged that the SUV's occupant restraint system was defective in that it failed to maintain him adequately in his seat. Plaintiff argued that safer alternative designs in use at the time included (1) a system with a friction lock latch plate, (2) integrated seat belts, (3) a torso belt web lock, and (4) a rollover-activated belt pretensioner.

After trial of the case resulted in a hung jury, the parties settled for a confidential amount.

Plaintiff's experts were Stephen Syson, automotive

design and occupant protection, Goleta, Cal.; and Anthony Sances, biomechanics, Santa Barbara, Cal.

Defendant's experts were Robert Gratzinger, seat belts, Irvine, Cal.; John L. Habberstad, accident reconstruction, and Jarrod W. Carter, biomechanics, both of Spokane, Wash.; and Edward A. Moffatt, automotive design and occupant protection, Orinda, Cal.

*Plaintiff's Counsel*

**Robert E. Ammons,** Houston, Tex.

**Matthew J.M. Prebeg,** Houston, Tex.

**James S. Rogers,** Seattle, Wash.

### **Plaintiffs may rely on circumstantial evidence in case alleging defective design of cruise control.**

*Knoster v. Ford Motor Co.*, 2006 WL 2561234 (3d Cir. Sept. 6, 2006).

The Third Circuit Court of Appeals held that plaintiffs in a lawsuit alleging defective design of a car's cruise control system may rely on circumstantial evidence because the case is one in which the product failure is manifest. Thus, the trial court erred in instructing the jury that plaintiffs needed to show proof of a reasonable alternative design.

In plaintiffs' claim alleging that the cruise control on their 1993 Ford Taurus malfunctioned, causing the car to accelerate out of control and crash, the trial court instructed the jury that to show design defect under New Jersey law, plaintiffs must offer proof of a reasonable alternative design. The jury found for defendant.

Reversing in part, the Third Circuit noted that although New Jersey law generally requires proof of a reasonable alternative design, the state has adopted § 3 of the Restatement (Third) of Torts: Products Liability. That section creates an inference that a product was defective at the time of sale or distribution, eliminating the need to prove specific defect, where plaintiff can show that the incident (1) was of a kind that ordinarily occurs as a result of a product defect and (2) was not solely the result of causes other than a product defect existing at the time of sale or distribution.

Addressing the first prong, the court said it is based on the premise that sometimes a product may fail so utterly—such as when an airplane loses its wings or a bicycle's brakes fail—that “common experience” indicates the product would not have failed absent a defect. Here, plaintiffs introduced evidence that the car accelerated suddenly without any input from the driver. If true, the court reasoned, the evidence suggests “the Taurus was as dangerous and as useless as a plane without wings or a bike without functioning

brakes.” Common experience dictates that so manifest a product failure would not occur absent some defect, the court concluded.

Turning to the second prong, the court said it requires that plaintiffs exclude other possible causes of the incident. Plaintiffs need not exclude other causes beyond all doubt, however. The question, the court said, is whether the evidence, if believed, permits an inference of defectiveness. Here, plaintiffs testified that the car suddenly and unexpectedly accelerated without any driver input, and their expert engineer testified that it did so as a result of its design. If believed, the court said, the evidence supports a jury finding that plaintiffs had excluded other possible causes.

Accordingly, the court remanded the design defect claim.

*Plaintiffs’ Counsel*

**Thomas J. Murray**, Sandusky, Ohio

Mary S. O’Neil, Sandusky, Ohio

*Comment:* The court also held that plaintiffs’ consumer fraud claim was not subsumed by the state products liability act because the claim seeks only economic damages resulting from harm to the car itself, and such damages are not recoverable under the act.

### **Tire: Tread separation: Rollover: Lack of nylon cap: Wrongful deaths: Settlement.**

*Valencia v. Goodyear Tire & Rubber Co.*, U.S. Dist. Ct., D.N.M., No. 05-941, Aug. 28, 2006.

Valencia was driving an SUV with his wife seated in the front passenger seat when the right rear tire, a Goodyear Radial ATR Pathfinder LT215/75R15, suffered a tread separation. Valencia lost control of the vehicle, which rolled over. Valencia and his wife, both in their 40s, were ejected and suffered fatal blunt-trauma injuries. Valencia is survived by four adult children from a previous marriage, and his wife is survived by three adult children from a previous marriage.

Two of the children, on behalf of their parents’ estates, and all of the children individually sued the manufacturer of the tire, alleging it was defectively designed in that it lacked nylon overlays, or caps. Plaintiffs claimed

that caps—bands of nylon that are wrapped around the circumference of the tire’s steel belts to restrict their movement and reduce stress at the belt edges—would have minimized the risk of tread separation and improved the tire’s performance.

Plaintiffs also alleged that the tire was defectively manufactured in that it lacked adequate adhesion between the belts.

The parties settled for a confidential amount.

Plaintiffs’ expert was David Osborne, tires, Wiltshire, Eng., U.K.

Defendant’s experts were James Gardner, tires, Akron, Ohio; and Juan Herrera, accident reconstruction, El Paso, Tex.

*Plaintiffs’ Counsel*

**Philip C. Gaddy**, Albuquerque, N.M.

**David J. Jaramillo**, Albuquerque, N.M.

### **Pickup truck: Rollover: Roof crushes in on driver: Insufficient roof strength: Defective design lacking B-pillar: Wrongful death: Settlement.**

*Noyes v. Ford Motor Co.*, U.S. Dist. Ct., D. Neb., No. 8-05-CV-00322, Aug. 2006.

Noyes, 65, was driving a 2000 Ford F-150 pickup truck on the highway when the vehicle became uncontrollable, veered off the road, and rolled over. During the rollover, the roof crushed in on Noyes, and he suffered fatal head trauma. He was retired at the time of his death and is survived by his wife, mother, and adult son.

Noyes’s wife, individually and on behalf of his estate, sued the manufacturer of the truck, alleging the roof was insufficiently strong to withstand the forces of a foreseeable rollover. Specifically, plaintiffs claimed the truck’s B-pillar had been designed out, compromising the strength of the roof structure.

The parties settled for a confidential amount.

*Plaintiffs’ Counsel*

**Jeffrey G. Wigington**,

**David L. Rumley**, and

Josh W. Hopkins, all of Corpus Christi, Tex.

Timothy L. Eves, Hunington, W. Va.

**Gary Nedved**, Lincoln, Neb.

## Concerns linger after FDA lifts ban on silicone breast implants

Concerns over the safety of silicone-gel breast implants linger after the FDA's decision in November to lift restrictions on their sale, returning them to the market for cosmetic use for the first time in 14 years.

The agency's decision granting Mentor Corporation and Allergan Corporation, formerly known as Inamed, final approval to market and sell silicone implants came just five months after a former Mentor scientist accused the company of withholding important test data from the FDA. In a June 2006 letter to the agency written after he was fired by Mentor, the scientist alleged that certain data previously submitted by the company—including “gel bleed” chemical test data pertaining to implant seepage—were inaccurate in light of later-discovered data the company never released. David Brown, *FDA Review Sought of Data on Implants*, Wash. Post (Oct. 13, 2006), available at [www.washingtonpost.com](http://www.washingtonpost.com).

The allegations, made public by Public Citizen in October after the FDA declined to act, prompted U.S. Senators Dianne Feinstein, of California, and Olympia Snowe, of Maine, to write the FDA urging it to withhold final approval until it had an opportunity to review the previously unreleased data.

“No medical device should be granted final approval if data that could reveal potential dangers has not been fully investigated and analyzed,” the senators wrote in an October 2006 letter to acting FDA commissioner Andrew von Eschenbach. Press Release, *Senators Feinstein and Snowe Call for Safety Review of Mentor Corporation's Silicone Gel Breast Implant*, Office of U.S. Sen. Dianne Feinstein (Oct. 20, 2006), available at <http://feinstein.senate.gov>.

In granting final approval, the FDA said an extensive review of data including the manufacturers' core studies, test results, and other clinical information provided “reasonable assurance” the implants are safe. But some safety and health advocates, lawmakers, and women's groups view the decision as politically motivated and say it leaves critical questions about implant safety unanswered.

*‘The most defective medical device ever’*

Calling the action “a triumph of corporate lobbying and hype over sound science and women's health,” Diana Zuckerman, president of the National Research Center for Women & Families, said the FDA's finding that silicone implants are “reasonably safe” is misleading.

“What does that mean?” she wrote in a statement issued after the FDA's decision. “In this case, it means that if a woman lives for 25 years after getting these

implants, she will need to remove them at least once, probably twice, and possibly more than that. If she doesn't, the implants are likely to break inside her body, and possibly leak silicone into her breasts, lungs, and other organs.” Press Release, *FDA Approves Silicone Breast Implants Despite Safety Concerns*, Natl. Research Ctr. for Women & Families (Nov. 17, 2006), available at <http://center4research.org>.

Citing high rupture rates, the need for repeat surgery, and evidence of lymph node infiltration and damage from leaking implants, Public Citizen Health Research Group director Sidney M. Wolfe called silicone gel implants the “most defective medical device ever approved by the FDA.” Wolfe said the decision “makes a mockery of the legal standard that requires ‘reasonable assurance of safety.’” Press Release, *Silicone Gel Breast Implants Most Defective Medical Device Ever Approved by the FDA*, Pub. Citizen (Nov. 17, 2006), available at [www.citizen.org](http://www.citizen.org).

The FDA's own scientists expressed concerns during the agency's review period. At an April 2005 hearing in which the advisory panel recommended denying Inamed's petition for premarket approval, panel members expressed concerns over potential health risks and the lack of adequate short- and long-term data. *Despite Unanswered Safety Questions, U.S. FDA Lifts Restrictions on Silicone Breast Implants*, Med. News Today (Nov. 20, 2006), available at [www.medicalnewstoday.com](http://www.medicalnewstoday.com).

Critics of the decision also accuse the agency of ignoring data suggesting a potential risk from platinum leaching from the implants. In a study reported in early 2006 in *Analytical Chemistry*, a journal of the American Chemical Society, researchers found high levels of a toxic form of platinum in the urine, hair, and breast milk of certain implant patients. The researchers concluded that the platinum, which had leached out of the implants, had transformed to an oxidized state that made it a potential source of severe allergic or toxic reactions. E.D. Lykissa & S.V.M. Maharaj, *Total Platinum Concentration and Platinum Oxidation States in Body Fluids, Tissue, and Explants from Women Exposed to Silicone and Saline Breast Implants by IC=ICPMS*, 78 *Analytical Chem.* 2925 (2006).

National Organization of Women (NOW) president Kim Gandy criticized the FDA for failing to follow up on the study. “Rather than attempting to replicate the study, FDA officials responded by dismissing it, following the lead of scientists who are paid consultants to implant makers,” Gandy said, noting that the agency has not required manufacturers to study the impact of silicone implants on breast milk, breast feeding, or the health of offspring born to women with implants. Gandy said NOW would be reviewing questionnaires

completed by mothers with implants detailing deformities and illnesses found in their children. Press Release, *FDA Approval of Dangerous Implants during Lame Duck Session Follows Pattern of Favoring Money and Politics over Science*, Natl. Org. of Women (Nov. 20, 2006), available at [www.now.org](http://www.now.org).

#### *Postsurgical concerns*

The FDA acknowledges that implants are likely to need replacement. The approval mandates labeling stating that the implants “are not lifetime devices” and that a recipient will likely need additional surgeries at least once over her lifetime. The required labeling also recommends that recipients have regular MRI screenings to check for rupture and warns that “the cost of MRI screening over a woman’s lifetime may exceed the cost of her initial surgery and may not be covered by insurance.”

Some physicians have expressed concerns over whether those recommendations are practical given that the cost of periodic MRIs and subsequent surgery may be out of many recipients’ price range. The decision also creates a “host of questions” for women considering the implants, according to Walter Erhardt, who chairs the American Society of Plastic Surgeons’ public education committee, such as what to do if the MRI scan detects a crack in the implant. By requiring periodic monitoring, the agency is suggesting that leakage may pose a health hazard, but surgeons are still divided on the question of whether breaks in silicone implants need to be replaced for safety. Melissa Healy, *Silicone: Now a Solid “Maybe,”* L.A. Times (Nov. 27, 2006), available at [www.latimes.com](http://www.latimes.com).

The FDA’s decision allows for the sale of Mentor and Allergan implants to breast reconstruction patients of any age and to breast augmentation patients ages 22 years or older. As a condition of approval, both manufacturers must track the safety and effectiveness of the implants in 40,000 women over 10 years and must study implant failures, among other conditions.

The FDA first banned silicone gel implants for cosmetic use in 1992, after reports that women were being injured by silicone leakage. Several years later, implant manufacturer Dow Corning agreed to pay \$3.2 billion to settle claims by more than 300,000 women alleging injury from ruptured implants.

#### **MEGA Brands settles magnetic toy lawsuits**

Canadian toy manufacturer MEGA Brands Incorporated has agreed to pay \$13.5 million to settle claims alleging injuries, including one fatality, caused by its Magnetix magnetic building sets. The sets, which were recalled last spring, consist of plastic building pieces and rods containing tiny magnets. The injuries occurred when the magnets came out of the plastic pieces and were ingested by small children, causing intestinal blockages and other complications.

By the time the manufacturer issued a voluntary recall of all 3.8 million sets last March, the U.S. Consumer Product Safety Commission (CPSC) had become aware of 34 incidents involving the toy, including the November 2005 death of a 22-month-old Washington state boy who suffered fatal intestinal injuries after ingesting the magnets. The magnets reportedly bonded together, causing an intestinal perforation and blood poisoning.

AAJ member Simeon J. Osborn, of Seattle, who handled the 14 cases involved in the settlement, said he was satisfied with the resolution. “I think the families were treated fairly and responsibly by MEGA Brands,” he said in a statement released by the manufacturer. “I am satisfied with the steps the company has taken to prevent such incidents in the future.” Press Release, *Mega Brands Settles Virtually All Product Liability Lawsuits and Claims*, MEGA Brands (Oct. 25, 2006), available at [www.megabloks.com/en/corpo/pdf/MagnetixSettlementRelease.pdf](http://www.megabloks.com/en/corpo/pdf/MagnetixSettlementRelease.pdf).

The settlement, reached in October and subject to court approval, includes no admission of liability by the manufacturer.

MEGA brands subsequently resumed sale of the toy after implementing improved manufacturing and quality control procedures and adding labels to the packaging warning of the risk of ingesting or inhaling the magnets.

Another magnetic toy danger surfaced late last year when the CPSC announced that it had received 170 reports of small magnets falling out of Polly Pocket magnetic play sets manufactured by Mattel, Incorporated. The sets consist of plastic dolls and accessories containing small magnets. The incidents included three reports of serious injuries to children who swallowed more than one magnet and suffered intestinal perforations requiring surgery. Mattel issued a voluntary recall of about 4.4 million of the play sets, including about 2 million sold outside the United States.

The Products Liability Law Reporter is unable to supply copies of articles. It does provide addresses of publications that may not be available at your local library.

### **ACE inhibitors increase risk of birth defects if taken during first trimester**

ACE inhibitors, which treat high blood pressure and were once thought to be safe when taken early in pregnancy, double the risk of babies being born with heart and brain problems if their mothers take the drugs in the first trimester, a recent study finds. William O. Cooper et al., *Major Congenital Malformations after First-Trimester Exposure to ACE Inhibitors*, 354 *New Eng. J. Med.* 2443 (2006).

### **Adverse drug events send 700,000 people to emergency rooms each year**

According to a recent study, adverse drug events, such as accidental overdoses and allergic reactions, send more than 700,000 people in the United States to emergency rooms each year. Daniel S. Budnitz et al., *National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events*, 296 *JAMA* 1858 (2006).

### **Canned, oily fish may lead to high mercury levels, premature births in pregnant women**

Researchers who studied more than 1,000 pregnant women in Michigan found that women who gave birth more than two weeks before their due date were more likely to have higher levels of mercury and ate canned, oily fish more often than women whose mercury levels were normal. Fei Xue et al., *Maternal Fish Consumption, Mercury Levels and Risk of Preterm Delivery*, *Envtl. Health Persp.*, Sept. 25, 2006, available at [www.ehponline.org](http://www.ehponline.org).

### **Media literacy training may discourage teen smoking**

A recent study finds that teens with above-average smoking media literacy—the level of awareness of advertisers' motives and methods—are half as likely to smoke as less media-literate teens, suggesting that media literacy training may be an effective tool in discouraging teenagers from smoking. *Get Wise to Subliminal Messages in Cigarette Ads: Teens Would Be Half As Likely to Smoke*, *Med. News Today*, Oct. 11, 2006, available at [www.medicalnewstoday.com](http://www.medicalnewstoday.com).

### **Nearly one-third of emergency contact information in FDA database is inaccurate**

A survey conducted by the FDA to assess the accuracy of the Food Facility Registration Database finds that about 30 percent of the emergency contacts for food companies are inaccurate. *About 30 Per Cent of Contact Information Inaccurate, Says FDA*, *FoodProductionDaily-USA.com*, Oct. 19, 2006, available at [www.foodproductiondaily-usa.com](http://www.foodproductiondaily-usa.com).

### **Nicotine replacement therapy may be riskier than going "cold turkey" for smokers in intensive care**

An examination of more than 200 records of smokers who were admitted to intensive care units finds that the patients who received nicotine replacement therapy had a greater incidence of death compared with the patients who did not receive nicotine. Roxanne Khamsi, *Nicotine Patches May Boost Intensive Care Risk*, *NewScientist.com*, Oct. 25, 2006, available at [www.newscientist.com](http://www.newscientist.com).

### **One-third of food packaging contains latex, U.K. study finds**

One-third of food packaging tested in a recent U.K. study was contaminated with latex, and latex was transferred to food in some instances, indicating a need for food packaging that contains latex to be labeled to avoid serious reactions in people with latex allergies. Joanna R. Topping et al., *A Preliminary Investigation into the Possible Transfer of Latex Allergens from Latex Protein Containing Materials in Contact with Food*, 86 *J. Sci. Food & Agric.* 1826 (2006).

### **Pharmaceutical industry funding for patient groups**

An investigation of pharmaceutical industry funding for patient groups finds that seven of the studied groups receive at least 20 percent of their funding from drug companies and that those groups were associated with conditions that affect many people and have therapies that require long-term treatment, providing marketing and profit potential. Jessica Marshall & Peter Aldhous, *Patient Groups Special: Swallowing the Best Advice?*, *NewScientist.com*, Oct. 28, 2006, available at [www.newscientist.com](http://www.newscientist.com).

### **Spinal fusion surgeries do not improve patients' disabilities, may increase risk of complications**

An examination of workers' compensation records in Washington finds that more than half of the workers who had spinal fusion surgery remained disabled two years after the procedures, indicating that the use of hardware to fuse vertebrae does not improve results and increases the risk of complications. Sham Maghout Juratli et al., *Lumbar Fusion Outcomes in Washington State Workers' Compensation*, 31 *Spine* 2715 (2006).

### **Study finds pesticide exposure is linked to Parkinson's disease**

A study on the link between pesticide exposure and Parkinson's disease finds that people with low level exposure to spray pesticides increase their risk of developing Parkinson's disease by 70 percent compared to those people exposed to very low levels or not exposed at all. Alberto Ascherio et al., *Pesticide Exposure and Risk for Parkinson's Disease*, 60 *Annals Neurology* 197 (2006).

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## UPDATES

*Garza v. Merck & Co.*, 25 PLLR 89 (June 2006): *award reduced*, Tex., Starr Co. 229th Jud. Dist., No. DC-03-84, Dec. 21, 2006. The trial court in this Vioxx case reportedly reduced the jury's \$25 million punitive damages award to \$750,000, the maximum allowed under a 2003 Texas law that caps punitive damages at twice the economic damages and an amount equal to any noneconomic damages awarded, not to exceed \$750,000. Because the jury's \$7 million compensatory damages award was

for noneconomic damages only, the award as reduced totals \$7.75 million.

*Price v. Philip Morris, Inc.*, 846 N.E.2d 597 (Ill. 2005), 25 PLLR 106 (June 2006): *cert. denied*, \_\_\_ U.S. \_\_\_, 2006 WL 1210502 (Nov. 27, 2006). The U.S. Supreme Court refused to review the Illinois Supreme Court's decision reversing a \$10.1 billion award to a class of smokers in this action alleging deceptive marketing of "light" cigarettes.

## COURT DOCUMENTS

*These documents are available for \$50 and can be downloaded from the Exchange at [www.exchange.justice.org](http://www.exchange.justice.org).*

**DUDLEY V. BUNGEE INTL. MFG. CORP.**, p. 10 (plaintiffs' statement of claims in a case alleging that a shock cord was defective because its warnings were inadequate and

its hooks were made from an inferior metal, among other reasons). No. PL568.

**HAHN V. L.C. INDUS.**, p. 10 (plaintiff's motion in limine in a case alleging a shock cord was unsafe in that it contained a hook that would open when stretched to length load). No. PL819.

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